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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------------|------------------|
| 10/084,839 | 02/26/2002 | Hatim Allawi | FORS-06666 | 6243 |
| 7590 | 09/21/2004 | | | |
| Mary Ann D. Brow MEDLEN & CARROLL, LLP Suite 350 101 Howard Street San Francisco, CA 94105 | | | EXAMINER PATTERSON, CHARLES L JR | |
| | | | ART UNIT 1652 | PAPER NUMBER |
| DATE MAILED: 09/21/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/084,839 | ALLAWI ET AL. |
| | Examiner Charles L. Patterson, Jr. | Art Unit 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 June 2004 and 16 August 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 46-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 46-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 February 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 46 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 5,846,717, claims 1-20 of U.S. Patent No. 5,985,557, claims 1-34 of U.S. Patent No. 5,994,069, claims 6,001,567 of U.S. Patent No. 6,001,567, claims 1-27 of U.S. Patent No. 6,090,543, claims 1-72 of U.S. Patent No. 6,348,314, claims 1-27 of U.S. Patent No. 6,458,535, claims 6-8 of U.S. Patent No. 6,555,357, claims 33-47 of U.S. Patent No. 6,562,611, claims 1-38 of U.S. Patent No. 6,692,917 and claims 1-26 of U.S. Patent No. 6,706,471. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the instant patents except for 6,555,357 and 6,562,611 are drawn to the invasive cleavage method of detecting the presence of a nucleic acid and since the components of claim 46 is drawn to a kit containing two of the elements of that method, it would have been obvious to one of ordinary skill in the art to make a kit of these elements in order to make it easier to perform the assay method. In indicated claims of patents 6,555,357 and 6,562,611 are drawn to kits comprising at least the elements of claim 46.

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The disclosure is objected to because of the following informalities:

Applicants list 10 applications in the oath filed 10/24/02 as being priority documents for this application. Applicants list 07/756,386 which correspond to D337,472, a design patent having nothing to do with the subject matter of the instant application. Perhaps the correct application number should be 08/756,386. All of the applications are listed as continuations in part. Because of scanning of the application into IFW and because of the inordinate size of the instant application file, some papers may have been omitted. Applicants are required to check the instant information and correct it appropriately. The first paragraph of the specification should be amended as appropriate since it does not agree with the oath.

On page 60 apparently "Figure 22" and "Figure 24" should be "Figure 22 A and B" and "Figure 24 A and B", respectively.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-48 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant claims are drawn to kits comprising a polypeptide of SEQ ID NO:2857 or encoded by SEQ ID NO:2856. The examiner has made a concerted ef-

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fort to find a substantial and specific asserted utility for this protein in the specification but has been unable to. On page 35, lines 27-29 it is stated that "the invasive cleavage structure...comprises an oligonucleotide comprising...SEQ ID NO:2837-4004". According to the sequence list and claim 48, SEQ ID NO:2857 is an amino acid sequence, not an oligonucleotide sequence so that this statement is apparently false. On page 273, lines 11-17 it is disclosed that the instant sequences are for the Taq(F28R)TthAKKCL mutant and corresponding nucleic acid encoding it. The examiner can find no other mention of the SEQ ID NOs or of the particular mutant in the specification, including the tables, or in the drawings. Therefore it is maintained that there is no specific and substantial utility asserted. Although the examiner has made a concerted effort to find a utility for the sequences and/or mutant, due to the voluminous size of the specification and drawing it is possible he made have missed something. If so, applicants should specifically point this out to him.

Claims 47-48 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The instant claim is drawn to "[a] kit for performing an invasive cleavage assay comprising a probe oligonucleotide and an invasive oligonucleotide configured to form an invasive cleavage structure in the presence of an RNA target nucleic acid". The claim contains no definitions of what "an invasive cleavage assay", "an invasive cleavage structure" or "an RNA target nucleic acid" is and without some such limitations in the claim, the specification is deemed to not be enabling for the instant claim. The specification does not teach one of ordinary skill in the art to make and/or use a kit for all such "invasive cleavage assays". The claim is deemed to read on a "probe oligonucleotide" and an "invasive oligonucleotide".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigma (U). The instant catalog discloses oligonucleotide markers on pages 1453-1457 and a anti-native DNA antibody kit on page 2515. Each of the marker kit contain several oligonucleotides and the DNA kit contains at least a DNA positive and negative control. It is deemed that this reads on the "probe oligonucleotide" and "invasive oligonucleotide" of the instant claim, without further definition in the claim.

The Xu, et al. reference crossed through in the enclosed PTO-1449 may be present but the reference submitted has no journal name, volume, or page

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numbers, so that the examiner is unable to ascertain what the reference is.

The other references crossed through were not present.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
September 17, 2004